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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,225	12/09/2003	Charles Price Taylor JR.	PC 25677A	4925

28880 7590 12/18/2006
WARNER-LAMBERT COMPANY
2800 PLYMOUTH RD
ANN ARBOR, MI 48105

EXAMINER	
GRAFFEO, MICHEL	
ART UNIT	PAPER NUMBER
1614	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/18/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,225	TAYLOR ET AL.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12,17,25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11,12,17,25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Action

Claims 1, 11-12, 17, 25 and 27 are examined.

Applicant has provided arguments for the patentability of claims 1, 11-12, 17, 25 and 27 in the response filed 3 August 2006.

Applicant's arguments, see response, filed 3 August 2006, have been fully considered but are not persuasive. Any rejection not specifically stated in this Office Action has been withdrawn.

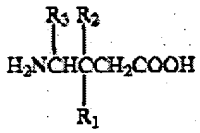
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 11-12, 17, 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,001,876 to Singh.

Singh teaches a method of treating fibromyalgia (in current claims 1, 11-12, 17, 25 and 27; see col 1 line 34) as well as other kinds of pain disorders such as trigeminal neuralgia, acute herpetic and postherpetic neuralgia, diabetic neuropathy, causalgia, brachial plexus avulsion, occipital neuralgia, reflex sympathetic dystrophy, fibromyalgia, gout, phantom limb pain, bum pain, and other forms of neuralgic, neuropathic, and idiopathic pain syndromes (in current claims 11 and 12; see col 1 lines 25-35) comprising a compound having the general structural formula:



Claims 1, 11-12, 17, 25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,635,675 to Kranzler et al.

Kranzler et al. teach the treatment of fibromyalgia (FMS) (in current claims 1, 11-12, 17, 25 and 27; see col 1 lines 5-30) comprising pregabalin (in current claims 1, 11-12, 17, 25 and 27; see col 7 line 65). Disorders associated with fibromyalgia are also treated such as fatigue, nonrestorative sleep, and memory difficulties wherein fatigue is characterized as chronic fatigue syndrome where patients generally report various nonspecific symptoms, including weakness, muscle aches and pains, excessive sleep, malaise, fever, sore throat, tender lymph nodes, impaired memory and/or mental concentration, insomnia, and depression (in current claims 11-12; see col 1 lines 15-

30). Like patients with FMS, patients with CFS suffer from disordered sleep, localized tenderness, and complaints of diffuse pain and fatigue.

Response to Arguments - 35 USC § 102

Applicant's arguments filed 3 August 2006 have been fully considered but they are not persuasive. Applicant argues that the '876 patent does not refer to the treatment of fibromyalgia. Examiner reproduces the part of the reference where treatment of chronic pain disorders is indicated in col 1 lines 26-27:

> Formula I below in the treatment of pain, especially for treatment of chronic pain disorders. Such disorders include,

The disorders are then listed and fibromyalgia is among such.

Applicant also argues that the '675 reference teaches the use of the claimed active as part of a combination therapy for the treatment of fibromyalgia. Since the claims are drafted with open language, the term "comprising", the teaching in the reference that the pregabalin is one of several compounds that can be adjunctively administered with NE 5-HT SNRI compounds, falls squarely within the instant claim language.

Claim Rejections - 35 USC § 103

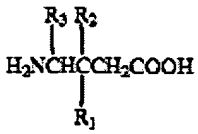
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 11-12, 17, 25 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent No. 6,001,876 to Singh in view of Guymer et al. An Aproach to Managing Fibromyalgia, Medicine Today (2002), pp 58-59, Vol 3(12) (cited by applicants on IDS filed 14 June 04 page 3 of 4).

Singh teaches a method of treating fibromyalgia (in current claims 1, 11-12, 17, 25 and 27; see col 1 line 34) as well as other kinds of pain disorders such as trigeminal neuralgia, acute herpetic and postherpetic neuralgia, diabetic neuropathy, causalgia, brachial plexus avulsion, occipital neuralgia, reflex sympathetic dystrophy, fibromyalgia, gout, phantom limb pain, bum pain, and other forms of neuralgic, neuropathic, and idiopathic pain syndromes (in current claims 11 and 12; see col 1 lines 25-35) comprising a compound having the general structural formula:



Guymer et al. further teach that there are a number of conditions associated with fibromyalgia including fatigue, sleep disturbance, distress, depression and irritable bowl syndrome for example.

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach the claimed invention as claimed. One of ordinary skill in the art would have been motivated to combine the references because both are directed towards the treatment of fibromyalgia and its associated disorders to the extent that Guymer et al. teach the applicability of treatment with antidepressants and Singh teaches that pregabalin is one such compound (see col 1 lines 15-20).

Response to Arguments - 35 USC § 103

Applicant's arguments filed 3 August 2006 have been fully considered but they are not persuasive. Applicant argues that one of skill in the art would recognize that efficacy for the treatment of fibromyalgia syndrome requires more than treatment with an analgesic agent. That may be true, but the PTO is not required nor is capable of making efficacy determinations. The teaching in the reference of the limitations in the claims is the standard for rejection. In this case, the references teach treating fibromyalgia with pregabalin and that is consistent with the scope and limitations of the claims.

Status of Art

For the purposes of the rejection under 35 U.S.C. 103(a), US Patent No. 6,635,675 to Kranzler et al. is considered an equivalent to US Patent No. 6,001,876 to Singh such that Kranzler et al. also teach the use of serotonin reuptake inhibitors (of which pregabalin is one – see col 7 lines 60-end of Krazler et al.).

Double Patenting

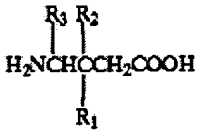
The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11-12, 17, 25 and 27 are rejected on the ground of nonstatutory double patenting over claims 1-15 of U. S. Patent No. 6,001,876 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully claimed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a method of treating pain comprising a compound having the general structural formula:



Although the claims do not specifically recite fibromyalgia, fibromyalgia is characterized by chronic pain and the specification of the '876 patent teaches the treatment thereof which the above compound.

Response to Arguments - 35 USC § 101

Applicant's arguments filed 3 August 2006 have been fully considered but they are not persuasive for the same reasons for the maintaining of the rejection over the '876 reference.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6 December 2006
MG

Ardin H. Marschel 12/10/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER